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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,933	10/27/2004	Donna L. Mendrick	GENE-035/15US	7118

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EXAMINER	
RIGGS II, LARRY D	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,933	MENDRICK ET AL.	
	Examiner	Art Unit	
	Larry D. Riggs II	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 12-21, 46, 48, 49, 53-56 and 61-63, drawn to a method of determining a compound's toxicity effect on gene expression of listed genes.

Group II, claim(s) 11 and 22, drawn to a method of predicting cellular pathways comprising detecting expression of genes associated with modulation of cellular pathways.

Group III, claim(s) 23-34, 50-52 and 65, drawn to sequence probes and sequence probes on solid supports that may hybridize listed genes.

Group IV, claim(s) 35-45, 47 and 64, drawn to a computer system comprising a user interface and database of information regarding hepatotoxin expression of listed genes.

Group V, claim(s) 57-60, drawn to a method of identifying an agent that modulates at least one activity of a protein.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The only feature uniting the inventions is a list of genes; this feature lacks novelty, see for example GenBank database.

Regarding Groups I, II, IV and V, each process is limited to comprising distinct process steps not required by the other methods which define a special technical

feature that is unique to each method. For example the method of Group I requires correlating a gene expression profile with toxic properties of a compound, which step is not required by the other methods. Likewise, Group II requires correlating an expression profile with modulation of at least one cellular pathway. Group IV requires using a computer to compare expression levels of genes and Group V requires assaying the activity of a protein.

Products of Groups III and IV clearly do not share a common special technical feature as the product of Group III has both the structural and functional characteristics of a nucleic acid or nucleic acid array and the product of Group IV is a computer system having neither the structure nor the function of a nucleic acid or array.

Finally, the product and process claims do not share a common special technical feature because the processes do not require that the steps be carried out using the products as claimed. Therefore no special technical feature unites the inventions.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Gene Election Requirement Applicable to All Groups

2. In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to measuring the gene expression resulting from a compound or agent's effect, or a probe interacting

with the listed tables of genes, the Applicants must elect a single sequence or a single combination of sequences as related to the category of tables listed in the claims. For example, Applicant might elect a specific gene for each table listed in claim 8.

As required in the MPEP §806.04(f), where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but no a second, while a second claim recites limitations disclosed only for the second species and not the first. The instant claimed species lack unity for the reasons indicated above with respect to the inventive Groups. Applicant is asked to recommend a sequence within the elected species set that the applicants believe to be novel for search purposes.

Species Election Requirement Applicable to Group I

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A single disease consisting of:

Carcinogenesis, cholestasis, hepatitis, liver enlargement, inflammation, liver necrosis, liver steatosis and peroxisome proliferation as recited in claims 20 and 21.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 20 and 21 each read on the claimed species.

The following claim(s) are generic: 7 and 9.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: They are different diseases and therefore, would presumably correlate with a distinct expression profile.

Second Set of Species Applicable to Group I

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A single toxin to be evaluated on cellular pathway modulation consisting of:

Acetominophen, 2-acetylaminofluorene (2-AAF), acyclovir, ANIT, AY-25329, BI liver toxin, chloroform, bicalutamide, carbon tetrachloride, chloroform, CI-1000, clofibrate, colchicines, CPA, diclofenac, diflunisal, dimethylnitrosamine (DMN), dioxin, 17alpha-ethinylestradiol, gemfibrozil, hydrazine, indomethacin, LPS, menadione, phenobarbital, tacrine, thioacetamide, valproate, Wy-14643 and zileuton as recited in claim 22.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claim 22 reads on the claimed species.

The following claim(s) are generic: 11.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding

special technical features for the following reasons: They are compounds of unrelated structure with unrelated effects on a cellular pathway.

Species Election Requirement Applicable to Group IV

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A hepatotoxin exposed to a tissue or cell to compare gene expression levels consisting of:

Acetominophen, 2-acetylaminofluorene (2-AAF), acyclovir, ANIT, AY-25329, BI liver toxin, chloroform, bicalutamide, carbon tetrachloride, chloroform, CI-1000, clofibrate, colchicines, CPA, diclofenac, diflunisal, dimethylnitrosamine (DMN), dioxin, 17alpha-ethinylestradiol, gemfibrozil, hydrazine, indomethacin, LPS, menadione, phenobarbital, tacrine, thioacetamide, valproate, Wy-14643 and zileuton as recited in claim 47.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claim 47 reads on the claimed species.

The following claim(s) are generic: 43.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: They are compounds of unrelated structure with unrelated effects on levels of gene expression.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry D. Riggs II whose telephone number is 571-270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DANIEL M. SULLIVAN, PH.D.
PRIMARY EXAMINER